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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,008	02/01/2005	Fumitaka Goto	01197.0247	4635

22852 7590 08/13/2007  
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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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08/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/523,008	Applicant(s) GOTO ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-16 is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**

**Claims 1 and 12-16 are pending in the application.**

***Election/Restrictions***

Applicant's election of Group I (Claims 1 and 12-16 - drawn to products) in the reply filed on April 5, 2007 was acknowledged in a previous Office Action. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Claims 2-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made

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**without** traverse in the reply filed on April 5, 2007.

Claims 2-11 have been cancelled per the Amendment filed July 31, 2007.

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffer {U.S. Pat. 3,493,582}.

*Determination of the scope and content of the prior art (MPEP*

*§2141.01)*

Applicant claims 4-nitro-imidazole compounds.

Hoffer teaches, and claims, antitrichomonal 4-nitro-imidazole compounds that are structurally similar to the instant claimed compounds. See in Hoffer, for example, the compounds of formula (1) wherein R<sub>2</sub> is halogen, A is nitro (see formula (VI) in column 2), B is hydrogen, and R<sub>1</sub> is 2,3-epoxypropyl (column 1 and column 3; and especially Example 11 in columns 5-6).

*Ascertainment of the difference between the prior art and the claims*

*(MPEP §2141.02)*

The difference between the compounds of the prior art and the compounds instantly claimed resides in that the prior art is silent as to the stereochemistry of the 2,3-epoxypropyl group.

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***Finding of prima facie obviousness--rational and motivation (MPEP  
§2142-2413).***

A stereoisomer is not patentable over its known racemic mixture unless it possesses unexpected properties not possessed by the racemic mixture. In re Anthony, 162 USPQ 594, 596 (1969) and In re Adamson, 125 USPQ 233, 234 (1960).

One skilled in the art would thus be motivated to prepare stereoisomers of the compounds taught by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful as chemotherapeutic agents. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

***Response to Arguments***

Applicant's arguments filed July 31, 2007 have been fully considered but they are not persuasive.

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Applicant argues that: (1) Hoffer broadly discloses nitroimidazole compounds; (2) the closest specifically made example in Hoffer has an iodine atom at the 2-position of the imidazole ring; and (3) the utility in Hoffer is different than that which is disclosed in the instant application.

All of Applicant's arguments have been considered but have not been found persuasive. As stated above, Hoffer teaches, and claims, antitrichomonal 4-nitroimidazole compounds that are structurally similar to the instant claimed compounds. Hoffer, per the general disclosure and the specifically made compounds, directs one skilled in the art toward the compounds instantly claimed.

Applicant argues that the specific examples of Hoffer have an iodine atom wherein the instant X variable can only represent the chlorine or bromine atoms. In response, it is well established that consideration of a reference is not limited to the

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preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 148 USPQ 507, 510 (CCPA 1966). Hoffer teaches that any halogen can be present on the 2-position of the imidazole ring (see in Hoffer wherein R<sub>2</sub> is halogen, column 1, line 45) and Hoffer defines halogen in column 1, line 72 through column 2, lines 1-3. Hoffer additionally teaches that bromine and chlorine are preferred (column 2, lines 2-3).

Further, there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness.

In re Dillon, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990). For all the reasons given above, the instant claimed invention would have been obvious to one



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skilled in the art. Therefore, the rejection is maintained.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will

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be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Allowable Subject Matter***

Claims 12-16 are allowed.

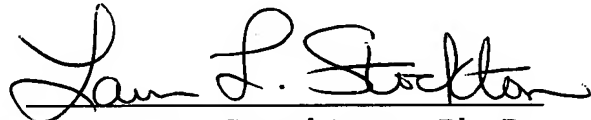
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact

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the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in cursive script, reading "Laura L. Stockton".

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

August 8, 2007